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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,426	08/21/2003	Michael Seul	LEAPS-C11	8876
7590 05/08/2006			EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022-7513			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/645,426	Applicant(s) SEUL, MICHAEL	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-92 and 114-142 is/are pending in the application.
- 4a) Of the above claim(s) 114-142 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 76-92, 114-142 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/21/04 + 8/21/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 114-142 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claims are drawn to a different invention which is different from the elected claims 76-92 because the invention of claims 76-92 are drawn to an array with "different" particle-attached ligands while the invention of the newly submitted claims 114-142 is drawn to an array of oligonucleotide-bearing beads in which the beads are not attached to "different" ligands as those in the elected invention. These inventions are unrelated because the array of claims 114-142 and the array of claims 76-92 are not usable together. One is an array of detecting only oligonucleotides and the other is an array of detecting different analytes at the same time. They have different effects and modes of operation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 114-142 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Amendment entry & Claim Status

The amendment filed on July 19, 2005 has been acknowledged and entered.

Claims 76-92 are being examined.

Newly submitted claims 114-142 are withdrawn from further consideration.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph is withdrawn herein.

Information Disclosure Statement

The information disclosure statement filed on December 29, 2003 and the supplemental IDS filed on August 8, 2005, fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it fails to provide any list of references. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 76-83, 86-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombinski (US 6,297,062).

Gombinski teaches a matrix of magnetic particles wherein each magnetic particle in the matrix is coupled to a specific species of a second member of the pair forming group present in a discrete location in the matrix, which is different than the location of the other magnetic particles. The second member is specific to the biological entities or ligand in the sample. A detectable label that specifically binds to the biological entity is added. The matrix can be a 96-dot arrangement corresponding to a pattern to the 96-pin device and 96-well format or a nitrocellulose sheet, a line, or a strip (see col. 5, lines 1-30; col. 12, lines 5-10; col. 15, lines 15-23). The particle-attached ligands encoded with a chemical or physical characteristic are equivalent to the magnetic particle-attached biological entities-label. Such magnetic particle-attached biological-label is attached to the substrate/matrix. The biological entities are proteins such as monoclonal antibodies or oligonucleotides such as RNA or DNA (see col. 3, line 64-col. 4, line 9). Pair forming group is two biological entities capable of affinity binding to each other. Examples are two complementary DNA sequences, antibody and antigen; streptavidin and biotin; etc. (see col. 4, lines 45-57). The labels are radioactive labels, fluorescent or chemiluminescent which is chemical tag and capable of interrogated optically. The particles are exposed to an aliquot of liquid containing an analyte. The ligands (DNA) are capable of hybridizing to analytes containing within the liquid volume. (see col. 13, lines 27-30). Regarding claim 91, Gombinski teaches that the matrix comprising several arrays. Gombinski also teaches that the particles are positioned randomly (see figure 1,

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col. 12, lines 15-31). Regarding the limitation of claim 88 "wherein the particles are attached to the substrate by chemical bonding", since it is drawn to a step of how the composition is made, it is not given any patentable weight because regardless of how the particles are affixed to the substrate, the structure of the result composition is not altered by such step. The particles are still affixed to the substrate. Regarding the limitation of claim 92, the location of each array indicates the types of ligands therein, Gombinski teaches that the location of the array can be stained with a dye or label so that it can be identified. (see col. 7, lines 16-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinski (US 6,297,062) in view of Nacamulli et al. (US 5,527,710).

Gombinski has been discussed above.

However, Gombinski fails to teach that the substrate is an electrode.

Nacamulli teaches antigen coated magnetic particles (particle-attached ligands) are deposited uniformly onto the working electrode from a flow stream by placing the magnet directly below. Electrochemiluminescent labeled antibodies are added and the labeled antibodies to the antigens on the magnetic bead immobilized on the surface of the electrode. (see col. 3, lines 10-30).

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It would have been obvious to one of ordinary skills in the art to use the electrode taught by Nacamulli as a substrate for use in the composition taught by Gombinski since both teaches that magnetic particles-attached ligands are immobilized to a substrate or an electrode and using chemiluminescent labels. Detection using an ECL label requires a substrate such as an electrode because electrical pulses are needed to apply in order to modulate the ECL output. The ECL signals are useful in monitoring the rates of binding between the proteins/reactants as well as detecting a low concentration of sample.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinski (US 6,297,062) in view of Hugl et al. (US 5,194,393).

Gombinski has been discussed above.

However, Gombinski fails to teach that the substrate is a semiconductor.

Hugl teaches a biosensor comprising a solid support such as a semiconductor; a layer of Langmuir-blodgett film attached thereto; at least one fluorescent dye which is located on top of the LB film; a receptor molecule located in or on the topmost layer of the LB film. (see col. 2, line 50-col. 3, line 35).

It would have been obvious to one of ordinary skills in the art to use the semiconductor solid support as taught by Hugl in the composition taught by Gombinski since both teaches that receptors and label particles such as fluorescent are immobilized on the substrate/semiconductor. Using a semiconductor as a solid support, one can measure changes in the surface potential at the interface of the medium and the insulative layer. By providing for reagents or protocols involving the

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assay medium, which result in a change in surface potential in relation to the present and amount of a particular analyte, measurement of the capacitance or related electrical determination can be related to the presence or amount of analyte in the assay medium.

Response to Arguments

Applicant's arguments filed on July 19, 2005 have been fully considered but they are not persuasive.

Regarding the 102 rejection by Gombinski, Applicants argue that Gombinski fails to teach "an array of several different particle-attached ligands wherein different ligands are attached to different particles and said particles have a chemical or physical characteristic that permits identification of the ligand or ligands attached thereto". Rather, Gombinski relates to a method of purification by "separating at least one species of biological entities from a sample solution" and there is no need for encoded particles, and no teaching of them. Applicants also point out that Gombinski coat the particles with the same functional group and the particles are not encoded with a "physical or chemical characteristic".

The present claims require an array of "different particle-attached ligands" wherein different ligands are attached to different particles.

Gombinski satisfies this requirement by teaching a matrix of magnetic particles wherein the magnetic particles comprising of various sizes (see col. 4, lines 13-14), are coated with different species, such as a first magnetic particle coupled to antibody against protein A, a second magnetic particle coupled to an antibody against protein B,

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and a third magnetic particle coupled to an antibody against protein C, (see col. 7, lines 5-15).

The present claims also recite that the beads have a "chemical or physical characteristic that permits identification of the ligand or ligands attached thereto".

Gombinski teaches that the location of a specific species in the matrix can be known by staining the magnetic particle matrix by means well known in the art, such as by enzymatic reaction, immunoreactions, use of fluorescent or radioactive labels and the like). (see col. 8, lines 15-22). Gombinski also teaches that the magnetic particles coupled to the species can be probed with detectable markers by contacting with enzymatic reactions, labeled complementary DNA fragments, staining with specific dyes (see col. 12, lines 49-50).

Gombinski also teaches in col. 11, lines 15-20, that his invention enables simultaneous different detections of several species of biological entities of the same sample solution. For example, it is possible to detect simultaneously all different species of bacteria present in one sample.

Furthermore, in response to Applicants' argument about the beads are coated with the same functional group, Gombinski also teaches that "it was possible to use different (functional) affinity particles at predetermined locations .." (see col. 16, line 67-col. 17, line 2). Thus, different species specific for a functional group can be coupled to particles bearing different functional groups.

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Applicants also submit that Gombinski does not disclose an array but merely a stripped matrix of magnetic particles, or a uniformed matrix, which generally will not be planar.

The present invention does not exclude that the planar array cannot be a stripped matrix or a uniformed matrix. However, Gombinski's matrix is indeed a planar array because the magnetic particles are arranged in a pattern on a planar matrix.

Regarding the 103 rejection by Gombinski in view of Nacamulli, Applicants argue that Nacamulli does not disclose the claimed beads because the reaction rate is determined by monitoring luminescence intensity of one type of reaction and that reaction produces a change in luminescence intensity and thus, there is no motivation to combine.

Since Gombinski teaches the claimed beads, and that Nacamulli teaches magnetic beads immobilized on an electrode, it would be obvious to immobilize such beads taught by Gombinski on an electrode for the reason set forth in the previous office action. The rejection is maintained.

Regarding the 103 rejection by Gombinski in view of Hugl, Applicants argue that there is no reason to combine the two references with or without Gombinski.

Since Gombinski satisfies the requirements of the claimed invention as discussed above and Hugl is relied upon for teaching of a semiconductor, it would have obvious to combine the two references for the reason set forth in the previous office action. Thus, the rejection is still maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

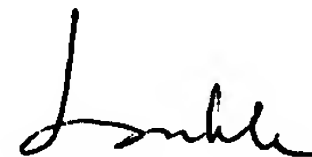
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
March 30, 2006



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SUPERVISORY PATENT EXAMINER
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04/03/06